UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

United States of America *ex rel.*

BRIAN G. FRIEDMAN
c/o Helmer, Martins, Rice &
Popham Co., L.P.A.
600 Vine St., Suite 2704
Cincinnati, OH 45202

Relator,

BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA

c/o Hon. Carter Stewart
United States Attorney
220 U.S. Courthouse
100 East Fifth Street
Cincinnati, OH 45202

and Hon. Eric Holder
Attorney General of the United States
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Plaintiffs and Relator

v.

Thornhill Research, Inc.
210 Dundas St., W, # 200
Toronto, ON Canada M5G 2E8
Statutory Agent for Service:
Corporation Service Company
2711 Centerville Suite 400
Wilmington, DE 19808
(additional defendant on next page)

Civil Action No. 1:14CV777

Judge J. BARRETT

COMPLAINT AND JURY DEMAND

ORIGINAL COMPLAINT
FILED IN CAMERA
AND UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

and :
:
Cliff Ansel :
210 Dundas St., W, # 200 :
Toronto, ON Canada M5G 2E8 :
:
Defendants. :

INTRODUCTION

1. This is a *qui tam* action brought by Relator Brian Friedman under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, in the name of the United States to recover damages, civil penalties, and other relief due to false and fraudulent statements, records, or claims made or caused to be made to the United States by Defendants Thornhill Research, Inc. (Thornhill) and Cliff Ansel (Ansel) by providing defective and noncompliant Portable Patient Transportation Life Support System devices (Life Support Devices) known as MOVES and MOVES SLC to the United States Marine Corps (USMC).[1] Such devices are intended to provide critical and life saving assistance for wounded Marines, airmen, and sailors.

2. The MOVES device is an integrated portable Intensive Care Unit (ICU) that combines an oxygen concentrator, an oxygen saving ventilator, a suction system, and a vital signs monitoring module. Defendants tout the MOVES device as the first completely integrated portable ICU.[2] This is a photo of the MOVES device from Defendant Thornhill's website:

[1] MOVES stands for Monitoring Oxygen Ventilation and External Suction.

[2] Ex. 1, Defendant's Brochure for MOVES device.

3. Defendants' MOVES Life Support Device failed to comply with contractual requirements that it (1) be certified as airworthy and (2) have FDA certification. Furthermore, any FDA approval obtained by Defendants was fraudulently induced because Defendants failed to disclose to the FDA, as required by law, known poor test results concerning the safety and efficacy of the MOVES devices, including a comment by one Government tester that MOVES is a "death box."

4. Defendants knew that their MOVES Life Support Devices did not comply with required contractual specifications and military and FDA regulations governing the provision of such devices, and thus did not satisfy the Government's conditions of payment for these Life Support Devices. Therefore, in making claims for payment for their MOVES Life Support Devices, Defendants knowingly presented or caused to be presented false claims for payment or approval and/or knowingly made, used, or caused to be made or used false records or statements

material to false or fraudulent claims in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

PARTIES

5. Relator Brian Friedman is a citizen and resident of the State of Ohio and a United States citizen. Relator Friedman is CEO and part owner of Seavival, LLC (Seavival), an Ohio limited liability company based in Akron, Ohio. Seavival designs and manufactures emergency medical systems, including a Life Support Device called CATSS.

6. Thornhill is a Canadian corporation based in Toronto, Ontario. Thornhill Research is a spinoff company of University Health Network and is engaged in the design, manufacturing, and marketing of medical products, including Life Support Devices MOVES and MOVES SLC. According to Thornhill's website, Thornhill maintains a facility in Plano, Texas. Thornhill is registered with the Texas Secretary of State as a Delaware corporation.

7. Defendant Ansel is a Canadian resident and citizen and the President and CEO of Defendant Thornhill Research, Inc. Defendant Ansel was personally involved in negotiating Thornhill's contracts with the United States Government. Defendant Ansel also regularly travels to the United States to market Thornhill's MOVES device to the Government and to the private sector.

8. Over at least the past five years, Defendants have received nearly $25 million from the United States Government to research, develop, and manufacture the MOVES devices.[3]

9. At all material times, Thornhill's research, development, and manufacture of its MOVES device was funded exclusively by the United States.

[3] Specifically, the $25 million included payment for the six First Article Testing devices and the 68 MOVES devices delivered in 2013.

JURISDICTION AND VENUE

10. This action arises under the United States False Claims Act, 31 U.S.C. §§ 3729 *et seq*. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345.

11. Personal jurisdiction over the Defendants exists in this Court because the Defendants transact business in this District and acts proscribed by 31 U.S.C. § 3729 occurred in this District. Specifically, Defendants caused their MOVES devices to be tested by the Government in this District on February 15-19, 2010 at University Hospital in Cincinnati, Ohio, and Defendants' false claims for payment would have been submitted to and paid by the Defense Finance and Accounting Service (DFAS) in Columbus, Ohio.

12. Venue in the United States District Court for the Southern District of Ohio, Western Division is proper pursuant to 31 U.S.C. § 3732(a) since Defendants do business in this judicial district and acts proscribed by 31 U.S.C. § 3729 occurred in this District. Specifically, Defendants caused their MOVES devices to be tested by the Government in this District on February 15-19, 2010 at University Hospital in Cincinnati, Ohio, and Defendants' false claims for payment would have been submitted to and paid by the Defense Finance and Accounting Service (DFAS) in Columbus, Ohio.

13. There was no "public disclosure," as that term is defined in the False Claims Act, 31 U.S.C. § 3730(e)(4)(A), of the allegations and the transactions alleged herein.

14. Thus, to the extent that the United States has any knowledge of the false claims or statements alleged herein, Relator is the original source of that knowledge, as that term is defined in the False Claims Act, 31 U.S.C. § 3730(e)(4)(B), based upon his direct and independent

knowledge of information on which the allegations and transactions herein are based, which was voluntarily provided to the Government before this complaint was filed.

15. Relator learned of the allegations described in this Complaint through responding to various Government solicitations as described herein (including solicitations to which Thornhill also responded), his resulting private interactions with Government employees involved in the Life Support Device procurement, and through private communications with Seavival's teaming partners who worked together with Seavival to respond to Government solicitations relating to Life Support Devices.

DEFENDANTS KNOWINGLY SUPPLIED THE UNITED STATES MARINE CORPS WITH CONTRACTUALLY NONCONFORMING LIFE SUPPORT DEVICES & SUBMITTED FALSE CLAIMS FOR PAYMENT OR APPROVAL AND FALSE RECORDS OR STATEMENTS MATERIAL TO FALSE OR FRAUDULENT CLAIMS TO THE UNITED STATES

A. The United States Marine Corps's Solicitations For Life Support Devices.

16. On March 6, 2011, the Marine Corp Systems Command (MARCOSYSCOM), issued a notice which sought to gauge industry capabilities for providing a Life Support Device. The device sought by MARCOSYSCOM was to be an integrated, portable, battery-powered device that will replace the existing ventilator, suction device, patient monitor, oxygen bottles and Special Medical Emergency Evacuation Device (SMEED) that was being used in the En Route Care System at the time.

17. In 2012, a formal solicitation was issued for a Life Support Device, Solicitation No. M67854-12-R-5062. Though there are several existing types of Life Support Devices in the industry, this Solicitation seemed specifically tailored to Defendants' MOVES Life Support Devices.

18. On July 16, 2012, Relator's company, Seavival, submitted a Proposal in response to the Solicitation offering to provide its CATSS device for $9,951,151.78.

19. On July 19, 2012, Seavival was notified by Mark Sanderson of the USMC that Seavival's demonstration of CATSS would take place on August 1, 2012 at 8:00 a.m. in Stafford, Virginia.

20. Seavival demonstrated its CATSS device as scheduled.

21. On September 12, 2012, Seavival was notified that it had been eliminated from the competition because its CATSS device was considered technically unacceptable pursuant to the Solicitation requirements.

22. The only other proposal submitted to the Solicitation was from Thornhill, which proposed to provide its MOVES devices for $37,846,916.06.

23. On October 23, 2012, MARCOSYSCOM awarded the contract to Thornhill. Thornhill delivered at least 68 MOVES Life Support Devices to the United States in 2013.

24. Apparently not satisfied with Defendants' Life Support Devices, on May 9, 2014 MARCOSYSCOM posted a new Solicitation (W911QYLIFESUPPORT) requesting information on the same Life Support Devices that were previously procured from Defendants through Solicitation M67854-12-R-5062 in 2012. It is Relator's belief that this new Solicitation was issued because the MOVES units delivered did not conform to contractual requirements.

25. Seavival responded to the 2014 solicitation as well. On August 1, 2014, members of MARCOSYSCOM made a site visit to Seavival to obtain information about the CATSS device and another End Route Life Support Device that Seavival was developing. To date, no further action has been taken concerning the May 9, 2014 solicitation.

B. Defendants Knowingly Supplied the United States Marine Corps with a Life Support Device Lacking Airworthiness Certification

1. By Contract the MOVES Devices Had to Be Certified to Airworthiness Requirements

26. Pursuant to the Performance Specifications for the Life Support Device, the device must provide a highly efficient ventilation, suction, oxygen generation and physiologic monitoring system for use by Navy medical personnel to evacuate and transport wounded Marines and Sailors from the battlefield.

27. These same Specifications require Life Support Devices to meet the following key performance requirements:

a. Operate in the expected medical evacuation flight profile of tactical helicopter/tilt-rotor aircraft including the CH-47, CH-53, MV-22 and UH-60.

b. Be certified for airworthiness on the CH-47, CH-53, MV-22 and UH-60. aircraft (mandatory); C-130 and other fixed-wing MEDEVAC/CASEVAC capable platforms (desired).

c. Be compatible with host aircraft platforms (CH-47, CH-53, MV-22, UH-60 aircraft (mandatory)), C-130 and other fixed-wing MEDEVAC/CASEVAC capable platforms (desired).

28. Airworthiness certification is required to eliminate any interference between the medical device and the aircraft and to protect the soldiers on board the aircraft.

2. Relator Learns That MOVES Had No Airworthiness Certifications

a. MARCOSYSCOM Lead Engineer David Keeler Provides No Documentation of Airworthiness to Relator

29. On August 1, 2014, MARCOSYSCOM Lead Engineer David Keeler visited Seavival in response to Seavival's proposal to the May 9, 2014 Solicitation. Relator discussed

Seavival's CATSS device with Mr. Keeler and showed him drawings of a new Life Support Device that Seavival was developing that was an integrated device similar to the MOVES Life Support Device.

30. During the site visit, Relator asked Mr. Keeler if MOVES had attained airworthiness certification. Mr. Keeler claimed MOVES had received airworthiness certifications three years earlier and that the certifications should be publicly available on the internet. Relator did an on-line search for the certifications but could not locate any of them.

31. On August 5, 2014, Relator emailed Mr. Keeler requesting copies of the Airworthiness Certifications for the MOVES devices.[4] Mr. Keeler's response states that he was attaching such certifications. But instead, Mr. Keeler emailed Relator pages from a Navy Tactical Reference Publication (NTRP) manual dated August, September, and November 2011 which state the initial version of the MOVES Life Support Device (P/N 100817) is authorized only on the MV-22B[5], CH-46E[6], and CH-53E.[7] Nowhere in the document is there any mention that the MOVES device has obtained airworthiness certification for any of these aircraft and the document nowhere mentions the UH-60 or the CH-47. To the contrary, the NTRPs discusses numerous shortcomings of MOVES including that the device has not been evaluated for its compatibility with the Navy operational electromagnetic environment, that its status light is not night vision goggle compatible, and that failure to cover the MOVES status light with black tape

[4] Ex. 2, 8/5/2014 Keeler and Friedman emails.

[5] *Id*., 8/4/2011 NTRP, at § 11.3.2.

[6] *Id.*, 11/10/2011 NTRP, at § 9.4.2.

[7] *Id*., 9/9/2011 NTRP, at § 11.4.

or dark cloth may result in degraded night vision goggle performance.[8]

b. JECETS Airworthiness Testing on the UH-60

32. On March 1, 2012, the Joint Enroute Care Equipment Test Standards (JECETS) were implemented by the United States Army Aeromedical Research Laboratory (USAARL), U.S. Air Force Aeromedical Branch (ASC/WNUP), and Aeromedical Test Laboratory (ATL). JECETS sets forth the test procedures that are required for medical equipment to be used onboard U.S. military transport, such as the MOVES device, during enroute patient care, including airworthiness certification. In order for medical equipment to be airworthiness certified for the U.S. Navy, Class Deck Managers at Naval Air Systems Command (NAVAIR) must give Navy Flight Clearance. JECETS sets forth the test methods for the C-130, UH-60, and CH-47, as well as other aircraft not at issue in this case. There are three phases of testing aeromedical equipment: 1) a baseline performance assessment; 2) laboratory tests; and 3) an in-flight assessment.

33. Pursuant to contractual requirements and the JECETS, Thornhill submitted six MOVES devices to the USAARL in Fort Rucker, Alabama. USAARL, pursuant to JECETS requirements, conducted airworthiness testing on the units from November 30, 2012 until April 17, 2013. After the testing is completed by the USAARL, MARCOSYSCOM must submit the USAARL report to NAVAIR which then evaluates the results and decides whether to approve the equipment as airworthy. That did not occur in this case because, according to an email that Relator received from Jeff Wallace at NAVAIR, MARCOSYSCOM never provided the test results to NAVAIR.

[8] *Id.*, 8/4/2011 NTRP, at § 11.3.3; 9/9/2011 NTRP at § 11.4.1; 11/10/2011 NTRP, at § 9.4.3.

34. In addition, the test on Thornhill's MOVES device only involved the UH-60 aircraft, whereas Thornhill's contract requires that the equipment be airworthiness certified for the CH-47, CH-53, and MV-22, in addition to the UH-60 aircraft. As such, even if NAVAIR had found the test results sufficient to certify MOVES for use onboard the UH-60, NAVAIR could not have certified MOVES as airworthy for use on the CH-47, CH-53, and MV-22 since no testing was ever performed on those aircraft.

c. MOVES and MOVES SLC Are Not Certified As Airworthy For the UH-60

35. A July 31, 2014 Department of Army memorandum from the Army Director of Aviation Engineering (which Relator obtained privately from a company that partnered with him on Life Support System solicitations) lists Patient Movement Items (carry-on medical equipment such as MOVES) which are authorized for use on the UH-60 helicopters.[9] Nowhere does Thornhill's MOVES device, MOVES SLC device, or any other Thornhill device appear on that list.

36. On January 30, 2013, a modification was issued to Solicitation No. W911QY19C0138 which was awarded to Thornhill to add "Airworthiness and FDA testing" to the MOVES SLC Life Support Device.[10] The modification provides as follows:

> The purpose of this modification is to add Airworthiness and FDA Testing to the MOVES System. The objective of this additional effort is to provide the enhanced capability of the MOVES system to the field through appropriate testing and preparation for FDA clearance. The contractor will support airworthiness testing of the MOVES SLC by a DoD test facility to be determined by the Navy, perform verification and validation bench testing of the MOVES SLC system, and

[9] Ex. 3, 7/31/2014 Department of the Army memorandum on Airworthiness Certifications for H-60 helicopters.

[10] Ex. 4, 1/30/2013, U.S. Army notice of modification to Solicitation No. W911QY19C0138.

complete a documentation package appropriate for submitting the MOVES SLC device to FDA.

37. Given MARCOSYSCOM's failure to provide any evidence of airworthiness certifications and the absence of Thornhill MOVES device on a recent listing of UH-60 approved in-flight medical equipment, it is apparent that Thornhill's MOVES device was never issued any airworthiness certifications for any of the aircrafts its device is onboard. The Government's January 30, 2013 solicitation modification which verifies that the MOVES device was not certified as airworthy further confirms the lack of airworthiness certification for MOVES.

38. Knowing that MOVES lacked airworthiness certification and thus did not satisfy contractual conditions of payment, Defendants nevertheless manufactured, assembled, and delivered to the United States Government MOVES devices and field level maintenance spare parts for use on board the UH-60, CH-47, CH-53, and MV-22 aircraft, including 68 devices which were to be delivered to the Government on or before February 28, 2014, and the six First Article Test devices delivered to the Government for airworthiness testing.

39. The Government paid Defendants $7,756,896 for these 68 MOVES Life Support Devices and field level spare parts.

C. Defendants Knowingly Supplied the United States Marine Corps with Life Support Devices That Lacked FDA Approval

40. Pursuant to the Performance Specifications, Technical Subfactors, and the Statement of Work for Solicitation No. M67854-12-R-5062, Thornhill was required to obtain Food and Drug Administration (FDA) 510K approval for its MOVES Life Support Device. Thornhill failed to comply with this requirement.

41. It is critical that the FDA be provided with accurate and up-to-date information on

the safety and efficacy of medical devices for use in this country. As a medical device manufacturer, Thornhill has ongoing and independent duties to disclose to the FDA all material information relating to the safety and efficacy of it MOVES device.

42. But, by failing to supply the FDA with a relevant study that criticized the safety, efficacy, and performance of the MOVES Life Support Device and that referred to it as a "death box," Defendants deceived the FDA into granting clearance to the MOVES and MOVES SLC devices and/or into allowing these devices to maintain clearance. Defendants then falsely certified to the Government that their MOVES Life Support Device had FDA clearance, when its FDA clearance of MOVES was fraudulently induced by Defendants' false statements to the FDA and active concealment of known critical safety and efficacy defects with the MOVES devices.

1. The FDA's 510(k) Disclosure Requirements

43. The 510(k) process requires medical device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. 42 C.F.R. § 807.81(a).

44. Manufacturers must compare their device to one or more similar legally marketed[11] devices and make and support their substantial equivalency claims. This can be accomplished by either filing a 510(k) summary (as described in 21 C.F.R. § 807.92) or a 510(k) statement (as described in 21 C.F.R. § 807.93). 21 C.F.R. § 807.87(h). Here, the Defendants filed 510(k)

[11] A "legally marketed device" is a device that was legally marketed prior to May 28, 1976, for which a premarket approval is not required, or a device which has been reclassified from Class III to Class II, or a device which been found substantially equivalent through the 510(k) process. 21 C.F.R. § 807.92(a)(3). A legally marketed device is commonly referred to as a "predicate" device. However, a legally marketed device does not include devices that are in violation of any part of the Food, Drug and Cosmetic Act (FDCA). A device may not be marketed in the United States until the applicant receives an order declaring that the device is substantially equivalent. 21 C.F.R. § 807.100(a)(5).

Class I devices are deemed to be the lowest risk. Class II devices are higher risk devices that require greater regulatory control. Class III devices are the highest risk devices

summaries for their MOVES devices.

45. Premarket summaries that rely on an assessment of performance data (as the MOVES devices' summaries did) **must** include:

> A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion **shall include**, where applicable, a description of the subjects upon whom the device was tested, **a discussion of the safety or effectiveness data** obtained from the testing, **with specific reference to adverse effects and complications**, and any other information from the clinical testing relevant to a determination of substantial equivalence . . . .

21 C.F.R. § 807.92(b)(2) (emphasis supplied).

46. Thornhill was also required to include a statement in its 510(k) summary that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. 21 C.F.R. § 807.87(k).

2. The FDA Regulations Requiring Manufacturers to Investigate Complaints

47. In addition, 21 C.F.R. § 820.198 requires manufacturers to maintain complaint files and to review, evaluate, and investigate any complaints involving the possible failure of a medical device.[12]

48. A manufacturer's failure to comply with the mandatory investigating and reporting requirements of Part 820, pursuant to 21 C.F.R. § 820.1(c), renders the device adulterated under section 501(h) of the Food Drug & Cosmetic Act (21 U.S.C. §§ 321-394), and the manufacturer is prohibited from selling the device in interstate commerce. 21 U.S.C. § 331(a)-(b).

[12] A "complaint" for purposes of Part 820 is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. 21 C.F.R. § 820.3(b).

49. As described more fully below in Section Five, testing done at the University of Cincinnati in 2010 which revealed numerous deficiencies in the MOVES device constitutes a "complaint" for purposes of Part 820 that should have been investigated and reported to the FDA pursuant to Part 803.

3. Thornhill's 510(k) Submissions to the FDA

50. Thornhill submitted an initial 510(k) premarket notification, which was received by the Department of Health and Human Services (HHS) on October 19, 2009, claiming that its MOVES device was substantially equivalent to other predicate life support devices and that it did not raise any new concerns about safety or efficacy.[13]

51. Thereafter, Thornhill obtained marketing approval for its initial MOVES device from the FDA on March 26, 2010.[14]

52. After its development of MOVES, Thornhill developed an updated version of MOVES called "MOVES SLC."

53. In 2014, Thornhill submitted a 510(k) application for its MOVES SLC Life Support Device.[15] Thornhill claimed in that application that the SLC version had added the following functionality to the previously cleared MOVES device:

- 12 Lead ECG capability

[13] Ex. 5-a. Thornhill's 510(k) summary for its MOVES device states that the device is considered a Class II medical device under 21 C.F.R. §§ 868.5925, 5440, 870.2300, 878.4780. *Id.*. at 1. Some of the citations in Thornhill's summary are erroneous. There is no 21 C.F.R. § 865.5870. Rather, the FDA regulation governing the non-breathing mask found is found in 21 C.F.R. § 868.5870, and the non-breathing mask is a Class I device, not a Class II device as set forth in Thornhill's 510(k) summary.

[14] Ex. 5-b.

[15] Ex. 5-c.

- A second temperature channel
- A third invasive pressure channel
- Removal of the requirement for use on MOVES O2 mask and replacement with a direct output from the onboard concentrator which is equivalent to the SeQual Eclipse 2 (K013931)[16]

54. In its 2014 510(k) application, Thornhill represented to HHS that the MOVES SLC was substantially equivalent to its prior MOVES device and to two other life support devices and that it did not raise any new concerns about safety or efficacy.[17]

55. MOVES SLC was not given 510(k) clearance from the FDA until May 29, 2014, the year after Thornhill sold 68 MOVES SLC devices to the Government.[18]

56. In the letters sent to Defendants granting 510(k) approval to the MOVES and MOVES SLC devices, the FDA also reminded Thornhill that it was responsible for complying with the FDCA's requirements, including registration and listing (21 CFR Part 807) and medical device-related adverse events reporting (21 C.F.R. Part 803).[19]

4. The FDA's Post 510(k) Clearance Adverse Event Reporting Requirement

57. The FDA is responsible for ensuring the safety and effectiveness of medical devices in the United States. A critical component of the FDA's information-gathering process after a device has been cleared or approved for marketing is adverse event reporting.[20] Such

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[16] Ex. 5-c.

[17] Ex. 5-c. Thornhill's 510(k) summary for its MOVES SLC device states that the MOVES SLC device is a Class II device under 21 C.F.R. §§ 868.5925, 868.5440, 870.2300, and 878.4780. *Id.*

[18] Ex. 5-d.

[19] Exs. 5-a, 5-d.

[20] *See* Adverse Event Reporting for Medical Device, OIG Report (October 2009), at pg. 1 available at http://hhs.gov/oei/reports.oei-01-08-0010.pdf.

reports provide the FDA with the most comprehensive source of information about the safety and effectiveness of medical devices and enables the FDA to take corrective action in order to prevent injury or death by alerting the public about potentially hazardous devices.[21] As such, the FDA has imposed several reporting requirements on medical device manufacturers regarding adverse events.

58. 21 U.S.C. § 360i(1) and 21 C.F.R. Part 803 require all medical device manufacturers to report any adverse events that have happened with any of their medical devices.

59. Pursuant to 21 U.S.C. § 360i(1), manufacturers must report to the Secretary when they become aware of events that reasonably suggest that one of their marketed devices:

> (i) may have caused or contributed to a death or serious injury; or
>
> (ii) has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

60. 21 C.F.R. § 803.10(c) further requires manufacturers to report the following:

> (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.
>
> (2) Submit reports of individual adverse reports no later than 5 work days after the day that you become aware of:
>
> > (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or
> >
> > (ii) A reportable event for which we made a request.
>
> (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

[21] *Id.*

61. A "malfunction" is defined as a "failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the devices. The intended performance of the device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4."[22]

5. Thornhill's Fails To Report An Adverse Event Which Exposes Safety Risks With The MOVES Devices To The FDA

62. Despite the clear dictates of the medical device laws and regulations discussed above, Defendants actively concealed and failed to report to the FDA significant safety risks and problems with its initial MOVES devices that were revealed by independent testing conducted in 2010.

63. In February 2010, an Early User Evaluation (EUE) was conducted by the Army Medical Department (AMEDD) Test Board (an Army entity) and the Air Force Medical Evaluation Support Activity (AFMESA), in conjunction with the Center for the Sustainment of Trauma and Readiness Skills (C-STARS), at University Hospital in Cincinnati, Ohio. Testing took place from February 15-19, 2010.[23]

64. The purpose of the EUE was to provide an initial assessment of the MOVES Life Support Device and two other Life Support Devices from other manufacturers.

65. The following findings were found by the testers regarding all three devices:

(1) None of the three systems as delivered and tested are ready to be introduced into an operational enroute critical care environment.

(2) At the devices' current maturity level, patient safety will be jeopardized

[22] 21 U.S.C. § 803.10(b)-(c).

[23] Ex. 6, Report of February EUE testing in Cincinnati, Ohio.

rather than enhanced.[24]

66. The following findings were made specific to Thornhill's MOVES device:

(1) The consensus among the EUE users was that **MOVES does not provide the advanced capabilities necessary for enroute critical care and is not suited for the critical care** transport mission moving patients from Level 2 facilities to Level 3 care and beyond.

(2) The consensus opinion was that **patient safety would be significantly compromised if MOVES were implemented** in place of the current portable medical equipment.

(3) Respiratory Therapists considered the MOVES ventilator to be the least capable of the three units, **not providing the advanced capabilities necessary to care for and transport critically impaired patients.**

(4) One EUE user commented **"This a death box."**[25]

67. The Life Support Devices were scheduled to undergo airworthiness testing at USAARL immediately after the EUE. However, due to the numerous safety issues uncovered by the testers in Cincinnati, it was recommended that the device makers be given another two months to address these issues. Two months after that it was recommended that an abbreviated EUE be conducted, pushing the project out to January 2011.[26]

68. Defendants would have received a copy of the EUE report and would have been apprised of these numerous safety and efficacy issues raised during the EUE.

69. Defendants were required to report to the FDA the safety and effectiveness data and adverse effects and complications stated in the EUE report in their 510(k) clearance approval applications for the MOVES devices, and/or as a post-clearance adverse event (pursuant to 21

[24] *Id.* at 2.

[25] *Id*. at 3. (emphasis added).

[26] However, that deadline was further delayed since the USAARL testing did not begin on the MOVES devices until late 2012.

U.S.C. § 360i(1) and 21 C.F.R. § 803.3).

70. However, no such disclosure appears in the summaries that Thornhill provided to the FDA to gain 510(k) clearance for its MOVES and MOVES SLC devices or in the FDA's Adverse Events database.

71. By knowingly failing to report the 2010 EUE to the FDA as required by law, Defendants fraudulently induced the FDA to give clearance to the MOVES and MOVES SLC devices and/or to allow these devices to maintain their clearance. Knowing full well that it had fraudulently obtained and/or maintained the FDA clearance for its MOVES and MOVES SLC devices, and that these devices thus did not satisfy the contractual conditions of payment that the device have FDA 510(k) approval, Defendants nevertheless manufactured, assembled, and delivered to the United States Government MOVES devices and field level maintenance spare parts for use on board the UH-60, CH-47, CH-53, and MV-22 aircraft, including 68 devices which were delivered to the Government on or before February 28, 2014, and the six First Article Test devices delivered to the Government for airworthiness testing.

72. By knowingly failing to report the 2010 EUE report to the FDA as required by law, Defendants also fraudulently induced the FDA to give clearance to the MOVES and MOVES SLC devices and/or to allow these devices to maintain their clearance by submitting false summaries for FDA approval for its MOVES and MOVES SLC devices and/or by submitting false summaries material to false or fraudulent claims for FDA approval for its MOVES and MOVES SLC devices. Without this fraudulently obtained FDA approval, the United States Marine Corps never would have accepted delivery of any MOVES or MOVES SLC devices and field level maintenance spare parts for use on board the UH-60, CH-47, CH-53,

and MV-22 aircraft, including 68 devices which were delivered to the Government on or before February 28, 2014, and the six First Article Test devices delivered to the Government for airworthiness testing. The Government paid Defendants $7,756,896 for these 68 MOVES Life Support Devices and field level spare parts.

73. By concealing the adverse report issued by the EUE, the FDA's ability to protect the public and United States military from the numerous problems with the MOVES device is obstructed and patients are being put at risk.

CLAIMS FOR RELIEF

COUNT I

Violations of 31 U.S.C. § 3729(a)(1)(A) - False and Fraudulent Claims to the United States Marine Corps

74. The allegations in the preceding paragraphs are realleged as if fully set forth below.

75. Defendants by and through their officers, agents, and employees knowingly, in reckless disregard, or in deliberate ignorance of the truth or falsity of the information involved knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval for MOVES and/or MOVES SLC Life Support Devices that did not satisfy contractual conditions of payment in violation of 31 U.S.C. § 3729(a)(1)(A).

76. Each invoice for payment Defendants submitted to the Government for payment, constituted a false or fraudulent payment.

77. The United States, unaware of the falsity of the claims and/or statements made by

Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may still be paying or reimbursing Defendants for MOVES devices delivered to the Government.

78. The United States has been damaged by and continues to be damaged by Defendants' false claims and fraudulent conduct.

COUNT II

Violations of 31 U.S.C. 3729(a)(1)(B) - False Records or Statements Material to False or Fraudulent Claims to the United States Marine Corps

79. The allegations in the preceding paragraphs are realleged as if fully set forth below.

80. Defendants, by and through their officers, agents, and employees knowingly, in reckless disregard or in deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be made or used, false records or statements material to a false claim submitted by Defendants, in violation of 31 U.S.C. § 3729(a)(1)(B).

81. Each representation Defendants made to the Government asserting that the MOVES Life Support Devices were safe for soldiers and in compliance with the applicable military standards and regulations and the terms of its contracts, constituted a false statement or record material to a false or fraudulent claim for payment.

82. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may still be paying or reimbursing Defendants for MOVES Life Support Devices delivered to the Government.

83. The United States has been damaged by and continues to be damaged by

Defendants' fraudulent conduct.

COUNT III

Violations of 31 U.S.C. § 3729(a)(1)(A) - False Claim For Approval to the United States Food and Drug Administration

84. The allegations in the preceding paragraphs are realleged as if fully set forth below.

85. In violation of 31 U.S.C, § 3729(a)(1)(A), Defendants knowingly, in reckless disregard or in deliberate ignorance of the truth or falsity of the information involved knowingly presented, or caused to be presented, and may still be presenting or causing to be presented to the United States Government, false or fraudulent claims for approval when they applied for approval of its 510(k) approval applications for the MOVES and MOVES SLC devices to the FDA, but falsely failed to disclose to the FCA adverse safety and efficacy data as required by law, including 21 C.F.R. § 807.92(b)(2).

86. These false claims for approval were material to the Government's 510(k) FDA approval of the MOVES and MOVES SLC Life Support Devices for human use. Absent this fraudulently obtained FDA clearance, the United States Marine Corps never would have purchased the MOVES and/or MOVES SLC Devices.

87. The United States has been damaged by and continues to be damaged by Defendants' fraudulent conduct.

COUNT IV

Violations of False Claims Act 31 U.S.C. § 3729(a)(1)(B) - False Record or Statement Material to a False or Fraudulent Claim to the United States Food and Drug Administration

88. The allegations in the preceding paragraphs are realleged as if fully set forth below.

89. Defendants knowingly violated 31 U.S.C. § 3729(a)(1)(B) by making, using, or causing to be made or used, false records or statements material to false or fraudulent claims for approval when Defendants applied for approval of their 510(k) clearance applications for the MOVES and MOVES SLC devices to the FDA, but the statements made in support of this claim for approval falsely failed to disclose to the FCA the adverse safety and efficacy data as required by law, including 21 C.F.R. § 807.92(b)(2).

90. The false statements, records, data, and Defendants' multiple failures to comply with its various duties of disclosure, investigation, testing, and reporting, were material to the Government's 510(k) FDA approval of the MOVES Life Support Device for human use. Absent this fraudulently obtained FDA approval, the United States Marine Corps never would have purchased the MOVES and/or MOVES SLC Devices.

91. Each representation the Defendants made to the Government asserting that the MOVES Life Support Device was safe for soldiers and in compliance with the applicable military standards and regulations and the terms of the contract, constituted a false statement or record.

92. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may still

be paying or reimbursing Defendants for MOVES Life Support Devices delivered to the Government.

93. The United States has been damaged by and continues to be damaged by Defendants' fraudulent conduct.

PRAYER

Relator, on behalf of himself and the United States Government prays:

(a) That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of $5,500 to $11,000 for each violation of 31 U.S.C. § 3729, and the Government for its expenses related to this action;

(b) That the Relator be awarded all costs incurred, including, but not limited to, court costs, expert fees, and all attorneys' fees and expenses incurred by the Relator in prosecution of this action;

(c) That in the event the United States Government intervenes in this action, the Relator be awarded an amount for bringing this action of at least 15%, to a maximum of 25%, of the proceeds of the action or settlement of the claim;

(d) That in the event the United States Government elects not to intervene in this action, the Relator be awarded an amount that is reasonable for collecting the civil penalty and damages, which shall be not less than 25% to a maximum of 30% of the proceeds of the action or settlement;

(e) That prejudgment interest be awarded; and

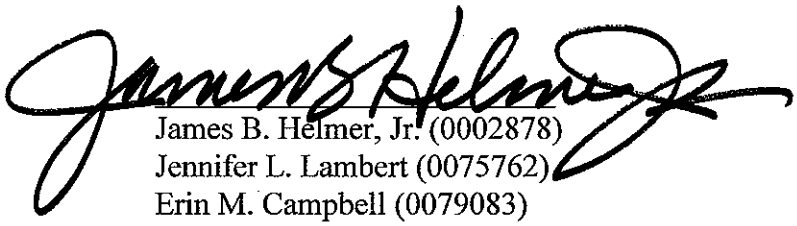
(f) That United States Government and Relator receive all relief, both in law

and in equity, to which they may reasonably be entitled.

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues.

Respectfully submitted,



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